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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,413	12/05/2005	Ulrich Loos	26465U	5027

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EXAMINER	
RIDER, LANCE W	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
03/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,413	LOOS, ULRICH	
	Examiner	Art Unit	
	LANCE RIDER	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *13-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/03/2005, 03/25/2005, 04/26/2005, and 12/05/2005.

The Non-final Office Action sent on February 26th 2010 is vacated in lieu of the Office Action below.

DETAILED ACTION

Status of Claims

Claims 1-12 and 30-39 are currently pending, claims 13-29 have been withdrawn due to the election requirement filed on September 2nd 2009.

Election/Restrictions

Claims 13-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 22nd 2009.

Applicant's election with traverse of Group I, claims 1-12 and 30-39 in the reply filed on December 22nd 2009 is acknowledged. The traversal is on the ground(s) that there is no serious burden to search the claims of the different groups. This is not found persuasive because the restriction was set forth under PCT rules 13.1 and 13.2 and not U.S. practice; search burden is not germane under the PCT rules.

Applicant's arguments that examination of all the inventions present in groups 1-4 would provide no further burden to the office were considered but not found persuasive. The inventions of groups 1-4 are drawn to distinct methods and products, each requiring

a separate search. Furthermore all of the groups require the search of different classes and subclasses, placing a serious burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statements (IDS)s, filed by applicant on March 3rd 2005, March 25th 2005, April 26th 2005, and December 5th 2005 have been considered by the examiner in the present case.

Claim Objections

Claims 2-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-12 recite the terms “characterized in that”, “in particular”, and ”preferably”, followed by further limitations. The phrases "characterized in that", “in particular”, and ”preferably” are all optional limitations which do not further limit the scope of claim 1.

Claim 4 recites the terms “ciglitazone and “rosiglitazone”. The examiner assumes that these are typographical errors for "cioglitazone" and "riosiglitazone”.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 30-39 provide for the "use of" or "method of using" PPAR-gamma and RAR/RXR ligands, but, since the claims do not set forth any steps involved in the methods, it is unclear what methods applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-12, and 30-39 are rejected under 35 U.S.C. 101 because the claimed recitation of a "use" or "method of use", without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 30-39 are so vague and indefinite that it is impossible to compare them to the prior art of record. The examiner has, therefore, made no attempt to examine these claims beyond rejecting them as indefinite and as being drawn to non-statutory subject matter.

With regard to claims 3-12 the claims omit any active steps. The claims recite "the method as claimed in claim 1 or 3" which have no active steps. The claims then

recite the terms “characterized in that”, “in particular”, and ”preferably”, followed by further limitations. The phrases "characterized in that", “in particular”, and ”preferably” all render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The claims also recite the term “and/or” which is considered indefinite. The methods require treatment "and/or" diagnosis. As treatment and diagnosis require different active steps it is not understood how one method performs both functions, either the method is for treatment or diagnosis. In reference to claims 3, 5, 7, and 10, either two or more compounds are required or they are not. Additionally, different steps would be required for diagnosis as compared to treatment.

In order to advance prosecution the examiner has construed claims 3-12 to be methods of treating given the statement in claim 3 requiring “treatment with active compounds”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta, R.G. et al., (Journal of the National Cancer Institute, 2000, provided in the IDS).

Mehta discloses the treatment of cancers with PPAR-gamma ligands and RAR/RXR ligands. The PPAR-gamma ligand used is the thiazolidinedione troglitazone, meeting the limitations of instant claims 3, 5-6, 8, and 11-12. (See the abstract.) It is also disclosed that PPAR-gamma receptors are thyroid hormone receptors, showing thioglitazone is a PPAR-gamma antagonist as claimed in instant claim 7. Mehta also discloses the RAR/RXR ligand can be trans-retinoic acid or 9-cis-retinoic acid, meeting the limitations of instant claims 5 and 6.

With regard to claim 4, the claim has been interpreted to not require a specific thiazolidinedione, as such troglitazone meets the limitation of a thiazolidinedione recited in claim 4. With regard to claims 8-10 the methods have been interpreted to not require the presence of a radioactive iodine or technetium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta, R.G. et al., (Journal of the National Cancer Institute, 2000, provided in the IDS) in view of Urban et al., U.S. Patent 5,814,647.

The following rejection was made interpreting the compounds recited in claim 4 as necessary limitations rather than optional limitations.

Mehta discloses treating cancers with troglitazone and retinoic acid as discussed above.

Mehta does not disclose the use of the thiazolidinedione cioglitazone.

Urban discloses the treatment of cancer with thiazolidinediones such cioglitazone and troglitazone. (See column 10, lines 29-35.)

Regarding the limitations in claims 11 and 12, Mehta discloses treatment of cancer with and RXR/RAR ligand and a PPAR-gamma ligand at the same time. Urban

discloses treating the cancer for multiple days with a PPAR-gamma agonist. Thus the combination of the two would include treating with a combine treatment of a RXR/RAR ligand and then treating with a PPAR-gamma ligand for several days thereafter.

The size of the cancer to be treated, the duration of the treatment, the dosages of ligands, etc. are all result effective parameters allowing for the optimization of a patients treatment. Adjusting all of these factors would have been within the abilities of one of ordinary skill at the time of the invention. A health care provider would have normally checked the condition of the patient and then administered care based upon the condition of the patient including factors such as the patient's age, weight, gender, progression of the disease, etc. and administered drugs accordingly. As such the dosage regimens and times provided would have be routine optimizations made by one of ordinary skill in the art at the time of the invention.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to substitute the cancer treating thiazolidinedione troglitazone in the cancer therapy methods disclosed by Mehta for the cancer treating thiazolidinedione cioglitazone disclosed by Urban in order to provide another equivalent cancer treatment method. Doing so is just the simple substitution of one art recognized equivalent cancer treatment for another.

Claims 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta, R.G. et al., (Journal of the National Cancer Institute, 2000, provided in the

IDS) and Urban et al., U.S. Patent 5,814,647 as applied to claims 3-12 above, and further in view of Mandell, R.B., et al., (Cancer Research, 1999).

The following rejection was made interpreting the compounds recited in claims 8-10 as necessary limitations rather than optional limitations.

Mehta and Urban teach methods for treating cancers using PPAR-gamma and RAR/RXR ligands.

Mehta and Urban do not teach using iodine, particularly ^{123}I and ^{131}I to kill NIS expressing cancers, particularly in thyroid cancers, or the use of technetium to diagnose such cancers.

Mandell teaches the use of I^{123} and I^{131} to kill cancer cells. (See the abstract and page 664, paragraph 4.) Mandell also teaches the use of technetium and radioactive iodine to monitor such tumors. (See page 661, paragraph 2.)

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the methods of treating and diagnosing cancers taught by Mandell with the methods for treating cancers disclosed by Mehta and Urban in order to form an improved methods of diagnosis and treating those same cancers. The skilled artisan would have been motivated to make this combination in order to both treat and image cancer tumors at the same time, allowing for improved patient treatment.

Conclusion

No claims are currently allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on M-F 11-12 and 1-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618